

REMARKS

Claims 11, 16-18, 20-27, 31-46 are presently pending in the application. Claim 11 has been amended. Claim 29 has been canceled without prejudice.

I. Rejection under 35 U.S.C. § 112 for Lack of Written Description

The Examiner has rejected claim 11, 16-18, 20-27, 29 and 31-46 under 35 U.S.C. § 112, first paragraph for failure to comply with the written description requirement. While not necessarily agreeing with the Examiner, the applicant has re-worded claim 11 as proposed by the Examiner. Accordingly, the applicant submits that the rejection is no longer applicable, and its reconsideration and withdrawal are requested.

II. Rejection under 35 U.S.C. § 112 for Indefiniteness

The Examiner has rejected claim 29 under 35 U.S.C. § 112, second paragraph, as it depends from a previously canceled claim. Claim 29 has been canceled; accordingly, the applicant submits that the rejection is no longer applicable, and its reconsideration and withdrawal are requested.

III. Rejections Under 35 U.S.C. § 103(a) for Obviousness

Claims 11, 16-18, 20-25, 26-42 and 43-46 have been rejected under 35 U.S.C. § 103(a) as obvious based upon:

- (i) United States Patent No. 6,379,654 to Gebreselassie et al. ("Gebreselassie") in view of U.S. Patent No. 4,148,872 to Wagenknecht et al. ("Wagenknecht"), or
- (ii) Gebreselassie in view of Wagenknecht and further in view of U.S. Patent No. 5,487,902 to Andersen et al. ("Andersen").

Applicants respectfully each traverse this rejection on the grounds that a *prima facie* case of obviousness has not been established in either instance.

The combination of Gebreselassie and Wagenknecht do not teach each and every element of the pending claims. Neither reference alone, nor the references in combination, teaches or suggests the process and stability limitations as recited in amended claim 11, *i.e.*, that the enzyme in the composition when incorporated in the recited manner will maintain substantially its initial activity at 23 °C for at least four weeks. It appears that the Examiner may be arguing that the prior art compositions

may exhibit such stability; however, no reasoning for this conclusion is provided. Applicant therefore respectfully submits that the Examiner has not met this element of the obviousness analysis.

Moreover, as discussed previously in the course of this prosecution, a person of skill in the art would not have been motivated to make the combination proposed by the Examiner to arrive at the present invention. Gebreselassie teaches that proteolytic enzymes, such as those used in the inventive composition are known to be unstable in a dentifrice environment, and that oral care compositions with enzymes therefore require enzyme stabilizing agents. Wagenknecht merely teaches tablet formulations with low levels of water; it is silent on the issue stabilization of enzymes. Thus, there would not have been any motivation to combine these references to arrive at the present invention.

Additionally, at the time the invention was made, there would be no expectation of success as a result. One of ordinary skill in the art would have expected upon viewing the two references in combination that it would have been impossible to incorporate an enzyme into a confectionary composition, because the optimal pH value could not be achieved in the manner taught by Wagenknecht in a chewing gum formulation versus a paste or gel formulation as taught by Gebreselassie. Even if the water amount were then increased to the levels taught by Gebreselassie in order to maximize the enzyme's stability and performance, the resultant composition would have a paste or gel consistency and thus fail as a chewing gum. The presently claimed invention provides an unexpectedly stable formulation in chewable confectionary form in the presence of a minimum of water.

With respect to the obviousness rejection of claims 25 and 43, As discussed above, Applicants maintain their assertion that the addition of Andersen to the teachings of Gebreselassie and Wagenknecht still does not render these claims obvious. Andersen does not cure the defects outlined above in the combined disclosures of Gebreselassie and Wagenknecht.

As discussed above, each of the claim limitations is not taught or suggested by the cited references; specifically, the references do not teach the process and enzyme stability limitations recited in amended claim 11.

Additionally, Gebreselassie teaches pastes and gels. Therefore, it is necessary that a skilled artisan, when viewing the teachings of Gebreselassie, would be motivated

to develop pastes and gels similar to those taught therein; not to confectionaries such as chewing gums. Even combined with the teachings of Wagenknecht, it would not have been obvious to vary the amount of water in such amounts in order to incorporate an effectively stabilize and optimize enzymes, while still retaining a low water concentration, as recited in present claims 25 and 43. Thus, claims 25 and 43 are not obvious in view of a combination of the teachings of the three references.

In view of the above, reconsideration and withdrawal of each of the obviousness rejections are requested.

CONCLUSION

In view of the above remarks, it is respectfully submitted that the claims are now in condition for allowance, early notice of which is earnestly solicited. Should any outstanding issues remain, the Examiner is invited to contact applicant's undersigned attorney at the telephone number below.

No fee is believed to be due for the filing of this *Amendment*. However, the Director is hereby authorized to charge any fees due, and credit any overpayments, to Deposit Account No. 03-2455.

Respectfully submitted,



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